

**Remarks**

In response to the Office Action mailed January 10, 2007, Applicants submit the following remarks. The one-month extended deadline for filing a response is May 10, 2007. Applicants submit herewith a one-month Petition for Extension of Time and the appropriate fees. Therefore, Applicants believe that this response is being timely filed. Applicants also submit herewith a Request for Continued Examination (RCE) and the appropriate fee. The RCE is submitted to allow entry and consideration of the above amendments. Applicants believe that the fees submitted herewith are sufficient. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-714.201.

By the above amendments, claim 1 was revised to more clearly set forth an embodiment of the invention wherein the method comprises rinsing with an amphiphilic wetting agent. This amendment is supported through out the specification as originally filed. See for example paragraph [0022].

Embodiments of the invention relating to chemical pre-etching, plasma treatment, heat treating, and rinsing with an alkaline detergent are now set forth in new claims 24-28. New claims 24-28 are based on claim 1 and claims 3-6.

Consistent with the amended claim 1 and new claims 24-28, claims 3-7 have been cancelled.

**Rejections under 35 U.S.C. 103**

Claims 1-3, 5-7, 12, 15-16, and 21 were rejected under 35 U.S.C. §103 as being obvious over Trimmer *et al.*, WO 96/1 0630 ("Trimmer"). Claims 8-10, 13, 17-19, and 22 were rejected under 35 U.S.C. §103 as being obvious over Trimmer in view of Baum, U.S. Patent No. 6,294,515. Claim 4 was rejected under 35 U.S.C. §103 as being obvious over Trimmer in view of Heinz *et al.*, U.S. Publication No. 2002/0012741 ("Heinz"). Claims 11, 14, 20, and 23 were rejected under 35 U.S.C. §103 as being obvious over Trimmer in view of Jam *et al.*, U.S. Patent No. 4,505,890 ("Jam"). These rejections are

respectfully traversed in as much as they are applied to the present claims for at least the following reasons.

A. The Present Claims

As defined by revised claim 1, the present claims relate to a method of coating the surface of one or more microprojections of a microprojection array comprising the steps of:

(i) providing a microprojection array comprised of one or more microprojections; (ii) treating the surface of one or more of said microprojections of the microprojection array with a method comprising rinsing with an amphiphilic wetting agent; (iii) providing a coating formulation comprising an active agent; (iv) applying the coating formulation to the treated surfaces of the one or more microprojections; and (v) drying the coating formulation onto the surfaces to form a coating.

B. The Applied Art

The applied references raise similar deficiencies and are therefore addressed as a group.

TRIMMER describes a method for introducing an agent into a cell. The method involves piercing the cell with microbarbs that contain the agent. BAUM discloses a low-foaming rinse agent based on sorbitol. HEINZ describes a method to apply a lubricant to the interior wall of a container, where the lubricant is irradiated with infrared radiation to attach the lubricant to the container wall. JAIN discloses an oral table for controlled release of a drug, where the table can be coated with a mixture of celluloses (Col. 6, lines 27-31).

C1. Analysis: Rejection over Trimmer

The legal standard for obviousness requires that three basic criteria be met (M.P.E.P. § 2143). The third criterion is that the prior art references (or references when combined) must teach or suggest all the claim limitations.

The method set forth in the present claims includes the feature of treating the surface of one or more microprojections. As mentioned above, this step is conducted prior to applying a coating formulation to the surfaces. The treating method comprises rinsing with an amphiphilic wetting agent.

Trimmer does not disclose or suggest treating microprojection with an amphiphilic wetting agent. Accordingly, applicants submit that the teaching in Trimmer does not teach or suggest all the claim limitations. Therefore, a prima facie case of obviousness has not been established. Withdrawal of the rejection under 35 U.S.C. §103 based on Trimmer is respectfully requested.

C2. Analysis: Rejection over Trimmer in view of Baum

Dependent claims 8-10, 13, 17-19 and 22, which relate to the embodiment of treating the microprojection surfaces with a wetting agent such as a surfactant. It is the Examiner's position that it would be obvious to apply the teaching of the low-foaming, sorbitol based surfactants of Baum, designed to prevent spotting and streaking of dishes in a dishwashing machine, to the teachings of Trimmer of a wetting agent included in a drug solution.

The legal standard for obviousness requires that the combined teachings of the prior art references teach or suggest all the claim limitations (M.P.E.P. § 2143). The combination of Trimmer and Baum fails to satisfy this requirement. Trimmer does not teach "treating" the surfaces of the microprojections, for the reasons given in C1 above.

Moreover, Baum does not satisfy this deficiency, since the rinse agents for dishes described in Baum may or may not be relevant for treating the surface of a material before application a drug coating formulation. Since neither Baum nor Trimmer teach treating the surface with a wetting agent, followed by applying a coating formulation to the treated surface, the combination does not teach or suggest all of the claim features.

Furthermore, the suggestion of the Examiner to include the rinse agents of Baum to the drug coating solution of Trimmer does not even capture the steps of applicants'

claim. In the instant claims, an amphiphilic wetting agent is used to treat the surfaces of the microprojections prior to applying a drug coating solution, rather than including a wetting agent in the drug formulation.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

C3. Analysis: Rejection over Trimmer in view of Heinz

Claim 4, now claim 26 was rejected based on the combined teachings of Trimmer with Heinz, relates to the embodiment where the treating step comprises plasma treating. It is the Examiner's position that it would be obvious to use a plasma treatment, mentioned by Heinz, as a pre-conditioning step for the microprobes of Trimmer, since Trimmer teaches several pre-conditioning steps.

In fact, the only pre-conditioning step taught by Trimmer is to soak the microprobes in ethanol and then rinse with water. As mentioned above, the other steps noted by the Examiner of cleaning, heating, and etching are not pre-conditioning, but formation of microprobes.

It would not be obvious to modify Trimmer to utilize a plasma treatment method as a microprobe pre-conditioning step based on the teaching in Heinz. The step of soaking microprobes in ethanol and rinsing with water is a cleaning step to remove surface impurities. In contrast, plasma treatment will result in etching of a surface or deposition of a material on a surface. Nothing in Trimmer suggests such a step prior to coating the microprobes. The mere mention in Heinz that plasma treatment is a conventional step of pre-conditioning is in the context of applying a silicone coating to plastic syringes. This mention does not guide one to apply plasma treatment to the microprobes of Trimmer in place of an ethanol soak followed by a water rinse, particularly since Trimmer has nothing to do with applying silicone to a plastic surface.

Thus, the rejection based on the combination of Trimmer and Heinz suffers from a failure of the combined teachings to show or suggest all of the claim limitations.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

C4. Analysis: Rejection over Trimmer in view of Jam

The Examiner asserts it would be obvious to take the teaching in Jam of a HPMC coating of an oral tablet and apply the HPMC as a wetting agent in the drug solution of Trimmer. This rejection is misplaced for the reasons given in C2 above, and primarily because this combination, as put forth by the Examiner, does not show or suggest the present claims. Applicants' claims recite treating the surface of the microprojections with, for example, an amphiphilic wetting agent, and then applying a drug coating formulation to the treated surfaces. The Examiner's line of reasoning suggests putting the wetting agent, HPMC, into a drug solution, which is not what the present claims recite.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

**Double-Patenting Rejection**

Claims 1-3, 5-7, and 15-16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,855,372 ("372 patent") in view of Trimmer. This rejection is traversed for at least the following reasons.

A. Legal Standard

According to M.P.E.P. 804(ii)(B)(1), in determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? The present claims are not rendered obvious over any of the claims of the '372 patent.

**B. Analysis: Rejection Based on the '372 patent combined with Trimmer**

Claims 1-12 of the '372 patent relate to a method for coating a liquid onto microprojections. None of the claims include a step of "treating the surface of one or more of said microprojections of said microprojection array with a method comprising rinsing with an amphiphilic wetting agent", as presently claimed.

Nor does Trimmer teach this step, for all the reasons given in above. Specifically, Trimmer fails to show or suggest treating the surface of a microprobe by rinse with an amphiphilic wetting agent.

Thus, the present claims are not merely an obvious variation of the claims in the '372 patent in view of Trimmer, since one of the claims steps is not taught. Therefore, withdrawal of the rejection for obviousness-type double patenting is respectfully requested.

## CONCLUSION

Applicants believe that, for the reasons explained above, all of the pending claims are in condition for allowance and therefore prompt and favorable action is respectfully requested. Applicants believe that this response is being timely filed. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-714.201.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2337.

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Respectfully submitted,

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